U.S. Department of Agriculture
U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING

BETWEEN

DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE

AND

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
BIOPESTICIDES AND POLLUTION PREVENTION DIVISION

AND

DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
BIOTECHNOLOGY REGULATORY SERVICES

Purpose:

The Environmental Protection Agency (EPA) has authority under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate biologically- and chemically-derived pesticides including microbial pesticides. Microbial pesticides have microorganisms (e.g., a bacterium, fungus, virus or protozoan) as the pesticide active ingredient. EPA has authority over the commercial use and field testing of microbial pesticides (http://www.epa.gov/pesticides/biopesticides/whatarebiopesticides.htm).

The Animal and Plant Health Inspection Service (APHIS) has authority under the Plant Protection Act of 2000 to regulate the importation, interstate movement and field release of biocontrol organisms. A biological control organism is defined in the statute as: "any enemy, antagonist, or competitor used to control a plant pest or noxious weed"[1]. Thus, the environmental releases of certain microorganisms are jointly regulated by EPA and APHIS.

[1] This authority includes genetically engineered organisms whose oversight is administered by Biotechnology Regulatory Services. Nonengineered organisms are administered by Plant Protection and Quarantine.

This MOU describes how the U.S. EPA and USDA/APHIS can notify one another about the potential environmental release of microorganisms that might involve regulatory policy of our mutual programs.

Background:

At times, microbial pesticide agents fall under the authority of EPA, USDA/APHIS/PPQ, and/or USDA/APHIS/BRS. Areas of concurrent regulatory authority include plant pathogens that are to be used as microbial pesticides and microbial pesticides that have been genetically altered to enhance their pesticidal properties.

EPA/BPPD and USDA/APHIS have been aware of instances where developers of microbial pesticides have not obtained the necessary clearances from all the required offices prior to first time release of an organism into the environment.

It is not uncommon for EPA/BPPD products for registration and/or experimental use to be imported from outside the Unites States. Such importation requires a notice of arrival at the port of entry. There have been incidences in which the United States Customs Service has intercepted shipments of microorganisms that are intended to be distributed as pesticides that did not have an EPA registration or Notice of Arrival. EPA/BPPD has also been aware of cases in which microbial pesticide applicants did not obtain needed USDA/APHIS permits or were using a microbial pesticide in violation of the Plant Protection Act and permitting regulatory policy. USDA/APHIS has received permit applications for movement of microorganisms to be used for pesticidal purposes in the environment that did not have the needed EPA Experimental Use Permit.

Other concerns for both USDA/APHIS and EPA/BPPD relate to classical insect biocontrol and microbial soil amendments.

"Classical Insect Biocontrol" is where the microorganisms are to be released in small amounts over a large area by researchers or government agencies to try to establish a pathogen into pest insect populations so that no more treatment is necessary. Generally they are not marketable products; however, their use would require EPA registration as a pesticide, even if the release is under 10 acres. These pathogens are usually imported from the country where the invasive pest originated, and these exotic organisms require APHIS permits. Often the researchers are not aware of their EPA regulatory obligations.

Microbial soil amendments often involve multiple microbial agents that may or may not have associated pesticidal claims and whose taxonomy and origin are not always well defined. These products have the potential to have both plant pest and pesticide product potential. If these amendments are imported, and contain soil or plant debris, they may be prohibited entry into the U.S. and/or release into the environment.

Substance of the Agreement: USDA/APHIS/PPQ, EPA, and USDA/APHIS/BRS enter into this agreement to share, on a reciprocal and as-needed basis, information on microbial pesticides related to our respective programs regulating microorganisms. Under this agreement the subject parties will do the following:

1) EPA/BPPD will inform potential microbial pesticide registration applicants at pre-submission meetings or at other points in the process, that they should contact USDA/APHIS/PPQ or BRS, or other Federal Agencies as appropriate, to ensure compliance with those agencies regulations. For USDA/APHIS/PPQ, contact the Permit Unit at 1-866-524-5421, or refer to the website http://www.aphis.usda.gov/plant_health/permits/. For Biotechnology Regulatory Services (BRS) contact (301) 851-3886, or refer to http://www.aphis.usda.gov/biotechnology/permits.shtml.

2) EPA/BPPD will inform USDA/APHIS/PPQ of new microbial pesticide registrations and Experimental Use Permit applications via email with links to the Federal Register Notice of Receipt. If the microbial pesticide is genetically altered, EPA/BPPD will also inform USDA/APHIS/BRS of the application. EPA/BPPD will inform USDA/APHIS/BRS of small-scale field test notifications for genetically engineered microbial pesticides via email with links to the Federal Register Notice of Receipt, if applicable.

3) USDA/APHIS/PPQ will inform EPA/BPPD regarding potential environmental releases involving microbial pesticides via email after the application has been reviewed by PPQ. If the microbial pesticide is genetically altered, USDA/APHIS/PPQ will direct the application to USDA/APHIS/BRS. If an applicant requests a permit for a cumulative total of greater than 10 acres of land or one surface acre of water, PPQ will send the applicant directly to EPA as PPQ would not be the primary responsive agency during experimental testing. However, PPQ will continue to require import permits regardless of the regulatory status with EPA, e.g. registration, experimental use permit, etc.

4) USDA/APHIS/BRS will inform EPA/BPPD of release permit applications and petitions for deregulation involving genetically altered microbial pesticides using the form in Attachment I. USDA/APHIS/BRS will also inform USDA/APHIS/PPQ of the application using the form in Attachment I. EPA/BPPD will respond to USDA/APHIS/BRS as to whether an EPA Biotechnology Notification is required.

Liaison Officers:

USDA and EPA liaison officers are designated in the appendix to this MOU.

Period of Agreement: This MOU will become effective when approved by the indicated signatories for EPA, USDA/APHIS/PPQ, and USDA/APHIS/BRS, and will continue indefinitely and may be modified by mutual written consent. Any party may terminate this MOU by providing written notice to the other parties. The MOU termination will be effective upon the sixtieth calendar day following notice, unless a later date is set forth.

Limitations of Commitment: This MOU and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this MOU shall be expended in accordance with its terms and the manner prescribed by the fiscal regulations or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

Congressional Restriction: Under 41 USC 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise therefrom.

No Private Right of Action: This MOU does not create any right or benefit, substantive or procedural, enforceable by law or equity, by persons who are not party to this agreement, against EPA or USDA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside of EPA and USDA.

Approved and Accepted for EPA's Office of Pesticide Programs Biopesticides and Pollution Division	**Approved and Accepted for USDA's Animal and Plant Health Inspection Service/Biotechnology Regulatory Services**	**Approved and Accepted for USDA's Animal and Plant Health Inspection Service/ Plant Protection and Quarantine**
KEITH A. MATTHEWS, Director Biopesticides and Pollution Prevention Division Office of Pesticide Programs Office of Chemical Safety and Pollution Prevention Environmental Protection Agency 13 September 2012 Date	MICHAEL C. GREGOIRE, Deputy Administrator Biotechnology Regulatory Services Animal and Plant Health Inspection Service United States Department of Agriculture 9/20/2012 Date	REBECCA BECH, Deputy Administrator Plant Protection and Quarantine Animal and Plant Health Inspection Service United States Department of Agriculture 10/22/12 Date

APPENDIX

Liaison Officers:

A. For USDA's Animal and Plant Health Inspection Service/Biotechnology Regulatory Services:

John T. Turner, Ph.D., Director, Environmental Risk Analysis Program
Margaret Jones, Ph.D., Senior Biotechnologist

Environmental Risk Analysis Program
USDA APHIS BRS
4700 River Road, Unit 147
Riverdale, MD 20737

B. For USDA's Animal and Plant Health Inspection Service/Plant Protection and Quarantine:

Shirley A. Wager-Pagé, Ph.D., Assistant Director, Pest Permitting Branch, Plant Health Programs
Shailaja Rabindran, Ph.D., Senior Agricultural Microbiologist

Regulations, Permits, and Manuals
Plant Health Programs
USDA APHIS PPQ
4700 River Road, Unit 133
Riverdale, MD 20737

C. For EPA's Office of Pesticide Programs/Biopesticides and Pollution Prevention Division:

Sheryl Reilly, Ph.D., Senior Advisor for Regulatory Policy and Science
Kimberly Nesci, Acting Chief, Microbial Pesticides Branch
John Kough, Ph.D., Senior Scientist
Mike Mendelsohn, Senior Regulatory Specialist

Office of Pesticide Programs/Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460

Attachment I

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road, Unit 147
Riverdale, MD 20737

APHIS-BRS receipt of a permit application for the release of a genetically engineered microorganism

DATE: [XXX]	
TO: Dr. Sheryl Reilly, Senior Advisor for Regulatory Policy and Science US-EPA, BPPD Office of Pesticide Programs 1200 Pennsylvania Avenue, NW Mailcode 7511-P Washington, D.C. 20460	FAX: (703) 308-7026 PHONE: (703) 308-8269 Email: reilly.sheryl@epa.gov
TO: Shirley A. Wager-Pagé, Assistant Director, Pest Permitting Branch, Plant Health Programs USDA/APHIS/PPQ 4700 River Road, Unit 133 Riverdale, MD 20737	PHONE: (301) 851-2323 Email: shirley.a.wager-page@aphis.usda.gov

CC: Kimberly Nesci, nesci.kimberly@epa.gov John Kough, kough.john@epa.gov Mike Mendelsohn, mendelsohn.mike@epa.gov US-EPA, BPPD Office of Pesticide Programs 1200 Pennsylvania Avenue, NW Mailcode 7511-P Washington, D.C. 20460 **and** Shailaja Rabindran, shailaja.rabindran@aphis.usda.gov Pest Permitting Branch, Plant Health Programs USDA/APHIS/PPQ 4700 River Road, Unit 133 Riverdale, MD 20737	

RE: APHIS/BRS Field Release Permit [XXX] – For a genetically engineered microorganism [XXX].

BRS will remind the applicant that issuance of an APHIS permit or deregulated status, does not release the applicant from their obligation to submit a Biotechnology Notification (BN), Experimental Use Permit, or registration application to EPA in accordance with EPA regulations. The following CBI-deleted information is being provided to assist EPA in making a determination as to whether the proposed field release or deregulation requires a submission to EPA as a microbial pesticide. Please notify the permit reviewer if a determination is made that such a submission is required. When appropriate, the APHIS supplemental permit conditions will include language reflecting the requirement for an EPA submission.

If a copy of the permit application or information claimed as CBI is needed for EPA to make this determination, or to contact the permit applicant, please inform the permit reviewer assigned to the permit.

The BRS permit reviewers name and contact information:

Name:	
Phone Number:	
Email:	

The permit reviewer has provided the following information to the best of their knowledge, based on the permit application and proposed supplemental permit conditions.

Indicate Phenotype or Selectable Marker	Genes	Donors

Permit applicant's name:		
Number of releases		
Intended use of the organism		
Total size of the release		
Number of release site(s)		
Release on land and/or water?		
	Yes	No
Is the organism intended for use as a pesticide?		
Is the genetic modification expected to "impart or enhance" pesticidal properties?		
Did new pesticidal properties result from "deletions or rearrangements within a single genome" by introduction of the modified genetic material?		
Will there be any use on food or feed crops?		
If used on food or feed crops, will those crops be destroyed or used for experimental purposes only?		

Note to Biotechnologist (permit reviewer): Email completed form to Dr. Sheryl Reilly, reilly.sheryl@epa.gov, and Dr. Shirley Wager-Pagé, Shirley.a.wager-page@aphis.usda.gov and cc Kimberly Nesci, nesci.kimberly@epa.gov, John Kough, kough.john@epa.gov, Mike Mendelsohn, mendelsohn.mike@epa.gov, and Dr. Shailaja Rabindran, shailaja.rabindran@aphis.usda.gov

Attachment II

BioPesticides and Pollution Prevention Division
Office of Pesticides Programs
U.S. Environmental Protection Agency

BIOTECHNOLOGY NOTIFICATION REQUIREMENT DECISION FORM

Microorganism:	
Request source:	APHIS BRS: Permit File No:
Proposed testing, size and crops:	Less than 10 acres and any food or feed crops will be destroyed or used for experimental purposes only
Genetic Modifications or Nonindigenous Source:	

1. Is this a microbial pesticide?

2. Is the modification(s) to this microbial pesticide sufficient to require the researcher to submit a Biotechnology Notification to the Office of Pesticides Programs?

Analysis:

Reviewer: _____ Date: _____

Microbial Pesticides Branch
BioPesticides and Pollution Prevention Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency

Concurrence: _____ Date: _____

Microbial Pesticides Branch
BioPesticides and Pollution Prevention Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency

Microbial Pesticides Branch Chief: _____ Date: _____

Kimberly Nesci, Acting Chief
Microbial Pesticides Branch
BioPesticides and Pollution Prevention Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency

Background: The following language is from the regulation, 40CFR172.45:

(c) Small-scale testing that requires a Notification. As provided in paragraph (a) of this section, and notwithstanding any other approval by any governmental entity, EPA review and approval are required prior to the initiation of any small-scale test involving either of the following microbial pesticides:

(1) Microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.

(2) Nonindigenous microbial pesticides that have not been acted upon by the U.S. Department of Agriculture (i.e., either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with the USDA).

(d) Small-scale testing that does not require a Notification.

(1) Testing conducted with microbial pesticides identified in paragraph (c) of this section, but made exempt pursuant to Sec. 172.52, does not require a Notification. The following microbial pesticides (or classes of pesticides) are exempt from the notification requirement in paragraph (a) of this section:

(i) Microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material that has been deliberately modified.

cc: Sheryl Reilly, John Kough, Mike Mendelsohn, EPA/BPPD/MPB